IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WELCH ALLYN, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
	)	**JURY TRIAL DEMANDED**
IRHYTHM TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff, Welch Allyn, Inc. ("Welch Allyn") files this complaint against Defendant iRhythm Technologies, Inc. ("iRhythm"), seeking damages and other relief for patent infringement, alleging as follows:

Nature of the Action

1. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., including specifically 35 U.S.C. § 271, seeking relief arising out of iRhythm's infringement of U.S. Patent Nos. 8,214,007 (the "'007 Patent"); 8,965,492 (the "'492 Patent"); 9,155,484 (the "'484 Patent"); and 10,159,422 (the "'422 Patent") (collectively, the "Patents-in-Suit").

2. Welch Allyn is the owner by assignment of the Patents-in-Suit.

The Parties

3. Welch Allyn is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 4341 State Street Road, Skaneateles Falls, New York, 13153.

4. For over a century, Welch Allyn has been designing and manufacturing medical diagnostic equipment. Ever since 1915 when Welch Allyn made and sold the world's first

handheld, direct-illuminating ophthalmoscope—developed by Dr. Francis Welch and William Noah Allyn—innovation has been at the core of Welch Allyn's business. Welch Allyn assists healthcare providers (and ultimately, patients) in overcoming complex challenges to providing services by engineering products and solutions that enable healthcare providers to see more patients, perform more procedures, and provide better onsite care.

5. Upon information and belief, iRhythm is a corporation organized and existing under the laws of the State of Delaware since September 14, 2006.

6. Upon information and belief, iRhythm has its headquarters and principal place of business at 699 8th Street, Suite 600, San Francisco, California, 94103.

7. According to iRhythm's website, iRhythm is a "digital healthcare company that creates trusted solutions that detect, predict, and prevent disease. Combining wearable biosensors and cloud-based data analytics with powerful proprietary algorithms that distill data from millions of heartbeats into clinically actionable information."

8. According to iRhythm's 2022 Form 10-K, iRhythm "offer[s] remote cardiac monitoring technology and also function[s] as [a] diagnostic service provider[]."

9. iRhythm and Welch Allyn are and have been competitors in the cardiac or ECG monitoring field.

Jurisdiction and Venue

10. This action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Upon information and belief, as a corporation organized and existing under the laws of the State of Delaware, iRhythm has substantial and continuous contacts with Delaware and has committed acts of infringement in Delaware sufficient to confer personal jurisdiction over iRhythm.

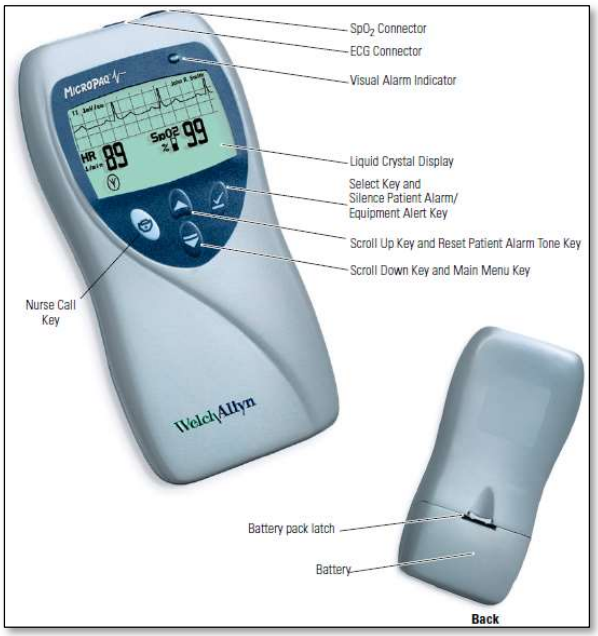
12. Upon information and belief, iRhythm is a commercial entity that makes, uses, advertises, offers for sale, and/or sells heart monitors, including but not limited to electrocardiogram (ECG) monitors and ECG monitoring services. iRhythm currently manufactures, makes, uses, advertises, offers for sale, and/or sells certain ECG monitoring products, including at least: (1) the Zio AT Monitor; (2) the Zio XT Monitor; and (3) Next-Generation Zio Monitor (the "Zio Monitor") (collectively, "ECG monitoring products" or "Accused Products").

13. Upon information and belief, iRhythm makes its Zio line of ECG monitors available to healthcare providers in Delaware.

14. Venue properly lies in this Court under 28 U.S.C. §§ 1391 and 1400(b) because iRhythm, as a Delaware-registered corporation, resides in Delaware.

Background

15. In 1915, Dr. Francis Welch and William Allyn founded Welch Allyn in New York and developed the world's first handheld, direct-illuminating ophthalmoscope. Dr. Welch received U.S. Patent No. 1,166,287, directed to this ophthalmoscope, on December 18, 1915.



16. The company later branched out into making various patient monitoring and diagnostic equipment. Welch Allyn continued its commitment to developing patient diagnostic solutions throughout the twentieth century. In the early 2000s, Welch Allyn acquired Protocol Systems, Inc., the developer of the Micropaq monitor, a revolutionary patient monitoring device.

17. The Micropaq monitor was a portable or wireless patient monitor for use by clinicians for single or multiparameter vital sign monitoring of ambulatory and nonambulatory pediatric and adult patients in health care facilities. *See* Ex. 1 at 1:28–32.[1] The Micropaq monitor's capabilities included measuring and reporting ECG waveforms, pulse oximetry (SpO_2), heart rate, and pulse rate data. The Micropaq monitor only worked as a telemetry monitoring system, and it had limited ability to operate standalone, particularly during connectivity disruptions.

18. While Welch Allyn's Micropaq monitor and other ambulatory ECG monitors such as the Holter monitor were revolutionary in that they allowed patients to enjoy at least some

[1] The specifications of the Patents-in-Suit are nearly identical. For simplicity, the '007 Patent specification will be cited as exemplary herein.

mobility, they had some disadvantages. Namely, these early ambulatory ECG monitors used multiple sensors or electrodes that had to be situated at precise locations on the patient's body to ensure accurate readings, and the sensors were connected to the portable unit by wires or leads.

19. In 2015, Welch Allyn was acquired by Hill-Rom Holdings, Inc. ("Hill-Rom"), a leading global medical technology company.

20. In 2017, Hill-Rom strengthened its focus on diagnostic cardiology and patient monitoring through its acquisition of Mortara Instrument, Inc. ("Mortara"), a leader in the field.

21. In 2019, Welch Allyn was awarded a 5-year $100M contract to supply patient monitoring systems, accessories, and training to the Army, Navy, Air Force, Marine Corps, and federal civilian agencies. This contract arrived on the heels of a previous 10-year contract in which Welch Allyn also supplied patient monitoring systems to the Armed Forces.

22. More recently, in 2021, Hill-Rom acquired Bardy Diagnostics, Inc. ("Bardy"), which was "a leading provider of ambulatory cardiac monitoring technologies." This latest acquisition brings together the innovative research and development teams of Mortara and Bardy with Welch Allyn.

23. Today, Welch Allyn continues to be a leading global manufacturer of physical examination instruments and accessories and EMR-connected vital sign and cardiac monitoring solutions. For example, through its Bardy division, Welch Allyn manufactures, markets, and sells the Bardy CAM Patch, a leading remote cardiac monitoring solution.

Patents-In-Suit

24. Early ambulatory monitors, such as the Micropaq and Holter monitors had several disadvantages. For example, the multiple wires are easily tangled and can cause discomfort or become unplugged when inadvertently pulled. Ex. 1 at 1:45–46. In addition, it is well-established that wire motion can increase ECG noise due to the triboelectric effect, which can negatively affect

the data. *Id.* at 1:47–48. Muscle movement can also increase ECG noise, due to the typical placement of ECG electrodes over major muscles, also negatively affecting the data collected. *Id.* at 1:48–50.

25. Unrelated to the electrodes and leads, other disadvantages of these early ambulatory ECG monitors included limitations of the batteries, which required routine recharging and/or replacement that was time consuming and costly. *Id.* at 1:50–52. Additionally, there is a need for these ambulatory ECG monitors to survive multiple defibrillation cycles of at least 360 joules. *Id.* at 1:53–55. Conventionally, this requirement has been met by one or more power resistors situated in series with the wire leads, but the physical volume of conventional power resistors was too large for use in a compact monitor application. *Id.* at 1:53–59.

26. Another disadvantage was the significant amount of power required to transmit large amounts of data, such as the full patient waveform that is required for a complete clinical analysis. *Id.* at 1:66–2:3. This power requirement restricts the design from being small and inexpensive. *Id.* Moreover, these early ambulatory ECG monitors were not well suited to be used in conjunction with an automated arrhythmia analysis because it was a computational intensive operation.

27. Welch Allyn's research and development teams understood these challenges and developed a new, body-worn ambulatory ECG monitor that combined a physiological sensor and a monitor in one. *Id.* at 2:8–10. This monitor was a single unit that could be directly and non-permanently affixed to a patient's chest. *Id.* at 2:10–11. This body-worn monitor also included a physically compact resistive element that was capable of protecting the device from multiple damaging defibrillation cycles. *Id.* at 2:11–14. Additionally, the body-worn monitor itself was able

to perform arrhythmia analysis and intelligently measure and transmit data only as required to alert clinicians of certain events. *Id.* at 2:14–19.

28. Beginning on November 1, 2006, Welch Allyn inventors sought patent protection for these important innovations across a family of patents. This new and innovative body-worn ambulatory ECG monitor allowed physicians and healthcare providers to more effectively and efficiently monitor their patients remotely for longer periods. Not only did the patented inventions improve the quality and amount of data collected, but it also significantly reduced the cost of monitoring patients over long periods of time remotely as opposed to having the patient remain in a clinical setting during the monitoring period.

29. In addition, these patented inventions allowed for reporting of serious cardiac events, such as atrial fibrillation ("AFib"). AFib is an irregular heartbeat, or arrhythmia. It is a serious condition that can lead to blood clots, stroke, heart failure, and other heart-related complications. According to the American Heart Association, over 12 million people are projected to have AFib by 2030.

30. On July 3, 2012, the '007 Patent was duly and legally issued for an invention entitled, "Body worn physiological sensor device having a disposable electrode module." A true and correct copy of the '007 Patent is attached hereto as Exhibit 1. The '007 Patent is assigned to Welch Allyn.

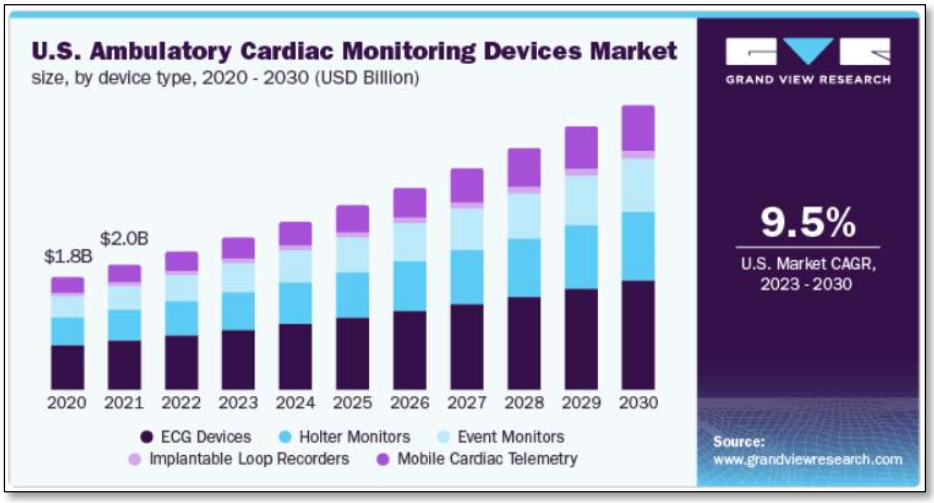
31. On February 24, 2015, the '492 Patent was duly and legally issued for an invention entitled, "Body worn physiological sensor device having a disposable electrode module." A true and correct copy of the '492 Patent is attached hereto as Exhibit 2. The '492 Patent is assigned to Welch Allyn.

32. On October 13, 2015, the '484 Patent was duly and legally issued for an invention entitled, "Body worn physiological sensor device having a disposable electrode module." A true and correct copy of the '484 Patent is attached hereto as Exhibit 3. The '484 Patent is assigned to Welch Allyn.

33. On December 25, 2018, the '422 Patent was duly and legally issued for an invention entitled, "Body worn physiological sensor device having a disposable electrode module." A true and correct copy of the '422 Patent is attached hereto as Exhibit 4. The '422 Patent is assigned to Welch Allyn.

Ambulatory Cardiac Monitoring Devices Market

34. The ambulatory cardiac monitoring devices market can be segmented into Holter monitors, ECG devices, event monitors, mobile cardiac telemetry, and implantable loop recorders. Ex. 5 at 1.



Id.

35. ECG devices accounted for the largest market share of 38.9% in 2022, and the demand for ECG devices is expected to continue to grow due to the increasing incidences of cardiovascular disease and hypertension worldwide, coupled with the ease of access, continuous monitoring, and high accuracy capabilities of the devices. *Id.* at 2. According to a study conducted

by the World Health Organization, 17.9 million people die every year due to cardiovascular diseases, which accounts for 32% of the total deaths globally. *Id.*

iRhythm

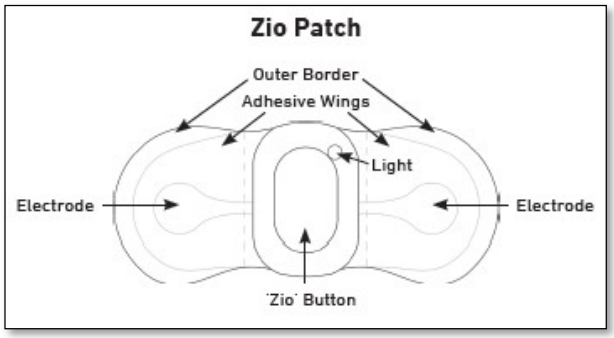
36. Upon information and belief, iRhythm was founded in 2006 and currently makes, uses, advertises, offers for sale, and/or sells the following ECG monitoring products: (1) the Zio AT Monitor; (2) the Zio XT Monitor; and (3) the Zio Monitor. *See* Ex. 6.

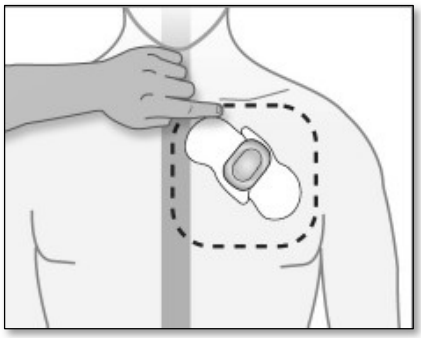
37. According to iRhythm's website, iRhythm's technology "combin[es] wearable biosensors and cloud-based data analytics with powerful proprietary algorithms, [and] distills data from millions of heartbeats into clinically actionable information."

iRhythm's Zio AT Monitor

38. The Zio AT Monitor is a single-patient-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. Ex. 7 at 2. The Zio AT Monitor itself, which includes an adhesive covering, is applied and adheres to the left side of the patient's chest, over the heart. *Id.* at 7, 12.

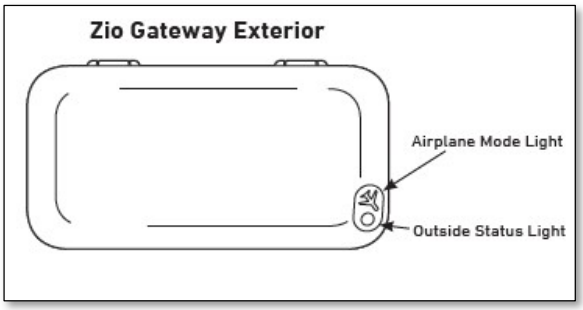
Ex. 6.

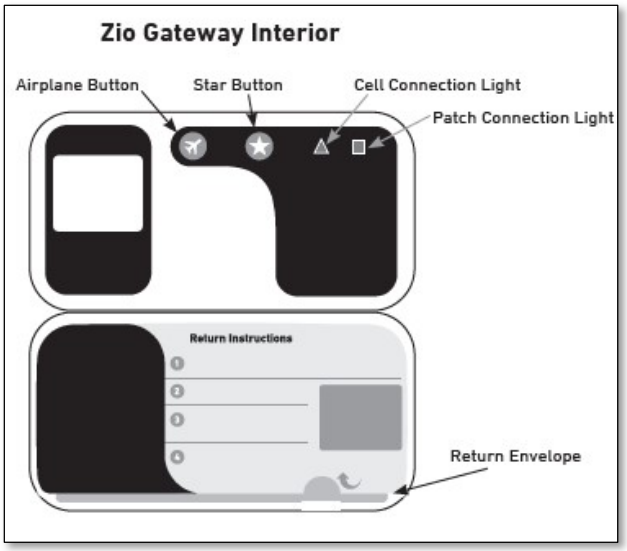




Ex. 7 at 7, 12.

39. Once the Zio AT Monitor is applied and activated, the monitor records the electrical impulses of the heart using two electrodes. The wireless transfer of data is enabled by the Zio AT Gateway. *Id.* at 2. The data is processed and analyzed for arrhythmia events, which are reported throughout the wear period. Ex. 8 at 20; *see also* Ex. 9 at § 3.1 ("Zio AT Gateway, The Gateway device transfers cardiac monitoring data to/from a Bluetooth radio to/from a LTE Cat M1 radio, powered by a single LiPo battery for up to 14 days."). At the conclusion of the wear period (up to 14 days), the patient removes the Zio AT Monitor and returns it, along with the Gateway, by mail to an iRhythm data processing center. Ex. 7 at 2. Upon receipt, the ECG data is further processed and a report is generated. *See id.*





Id. at 7.

40. Upon information and belief, iRhythm's Zio AT Monitor was approved by the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act on June 2, 2017. *See* Ex. 10. Upon information and belief, the Zio AT Monitor was originally called the Zio QX Monitor, but iRhythm rebranded the Zio QX Monitor as the Zio AT Monitor. *Compare* Ex. 10, *with* Ex. 8 at 20.

iRhythm's Zio XT Monitor

41. The Zio XT Monitor is single-use ECG monitor that can record up to 14 days of ECG data. Ex. 11 at 2. The Zio XT Monitor includes an adhesive covering, which is applied and adheres to the left side of the patient's chest. *Id.*; *see also* Ex. 12. The Zio XT Monitor records the electrical impulses of the heart using two electrodes, with the ECG recordings stored internally within the device. Ex. 11 at 2. At the conclusion of the wear period (up to 14 days), the patient removes the Zio XT Monitor and returns it by mail to an iRhythm data processing center. *Id.* Upon receipt the ECG data is further processed and a report is generated. *Id.*

Ex. 6.

42. Upon information and belief, iRhythm's Zio XT Monitor was approved by the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act on July 18, 2012. *See* Ex. 13. Upon information and belief, the Zio XT Monitor was originally called the Zio Patch, but iRhythm rebranded the Zio Patch as the Zio XT Monitor. *Compare* Ex. 13, *with* Ex. 14 at 5.

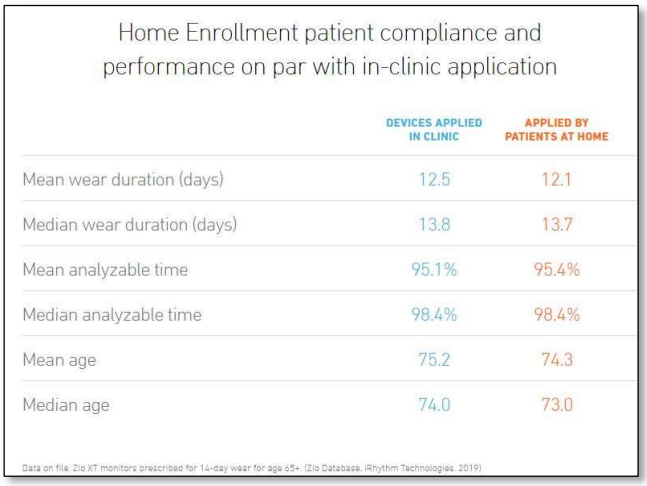
iRhythm's Next-Generation Zio Monitor

43. The Zio Monitor (also referred to as the "Next-Generation Zio Monitor") is similar to the Zio XT and AT Monitors but has an improved form factor, "which is 23% thinner, 62% lighter, and 72% smaller." Ex. 15 at 2; *see also* Ex. 16. iRhythm's Chief Technology Officer explained "miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing." Ex. 15 at 3.

Ex. 6.

44. Upon information and belief, the FDA approved iRhythm's Zio Monitor under Section 510(k) of the Federal Food, Drug and Cosmetic Act on May 21, 2021, as an updated version of the Zio XT Monitor. *See* Ex. 14.

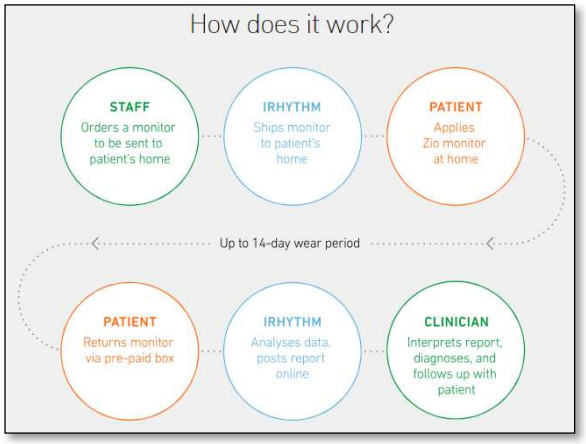
45. Upon information and belief, iRhythm makes the Accused Products available to patients directly or through healthcare providers. Ex. 17 at 2.



Home Enrollment patient compliance and performance on par with in-clinic application

	DEVICES APPLIED IN CLINIC	APPLIED BY PATIENTS AT HOME
Mean wear duration (days)	12.5	12.1
Median wear duration (days)	13.8	13.7
Mean analyzable time	95.1%	95.4%
Median analyzable time	98.4%	98.4%
Mean age	75.2	74.3
Median age	74.0	73.0

Data on file. Zio XT monitors prescribed for 14-day wear for age 65+. (Zio Database, iRhythm Technologies, 2019)



Id. at 2–3.

46. Upon information and belief, iRhythm manufactures the Accused Products in the U.S.

iRhythm's Knowledge of Welch Allyn's Patents-In-Suit

47. iRhythm has had knowledge of at least Welch Allyn's '007 Patent since at least August 10, 2021, when iRhythm submitted an Information Disclosure Statement during prosecution of iRhythm's U.S. Patent Nos. 11,350,864, listing the '007 Patent. *See, e.g.*, Ex. 18 at 3.

48. iRhythm has had knowledge, or in the alternative, has remained willfully blind of at least Welch Allyn's '492 Patent since at least August 10, 2021, when iRhythm submitted an Information Disclosure Statement during prosecution of iRhythm's U.S. Patent Nos. 11,350,864, listing at least one family member of the '492 Patent. *See, e.g.*, Ex. 18 at 3 (listing the '007 Patent).

49. iRhythm has had knowledge, or in the alternative, has remained willfully blind of at least Welch Allyn's '484 Patent since at least August 10, 2021, when iRhythm submitted an Information Disclosure Statement during prosecution of iRhythm's U.S. Patent Nos. 11,350,864, listing at least one family member of the '484 Patent. *See, e.g.*, Ex. 18 at 3 (listing the '007 Patent).

50. iRhythm has had knowledge, or in the alternative, has remained willfully blind of at least Welch Allyn's '422 Patent since at least August 10, 2021, when iRhythm submitted an Information Disclosure Statement during prosecution of iRhythm's U.S. Patent Nos. 11,350,864, listing at least one family member of the '422 Patent. *See, e.g.*, Ex. 18 at 3 (listing the '007 Patent).

COUNT I

Patent Infringement of U.S. Patent No. 8,214,007

51. Welch Allyn realleges and incorporates by reference the allegations in paragraphs 1–50 of this Complaint.

52. iRhythm makes, uses, sells, and/or offers for sale the Zio Monitor in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271(a), and, as set forth in the attached non-limiting Claim Chart (Ex. 19), iRhythm directly infringes at least claim 45 of the '007 Patent, either literally or under the doctrine of equivalents.

53. iRhythm has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from Welch Allyn and during the term of the '007 Patent.

54. Thus, iRhythm is liable to Welch Allyn in an amount that compensates it for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

55. As previously described, iRhythm's infringement has been done with full and express knowledge of the '007 Patent and is therefore deliberate, willful and wanton, as iRhythm has cited the '007 Patent on the face of several of its issued patents. *See, e.g.*, Ex. 18 at 3.

COUNT II

Patent Infringement of U.S. Patent No. 8,965,492

56. Welch Allyn realleges and incorporates by reference the allegations in paragraphs 1–55 of this Complaint.

57. iRhythm makes, uses, sells, and/or offers for sale certain Zio ECG monitoring products, including at least the Zio AT Monitor, Zio XT Monitor, and Zio Monitor. *See* Ex. 6. Any of these individual activities is an act of infringement under 35 U.S.C. § 271(a), and, as set forth in the attached non-limiting Claim Charts (Exs. 20–22), iRhythm directly infringes at least claim 1 of the '492 Patent, either literally or under the doctrine of equivalents.

58. iRhythm has engaged in the foregoing conduct with respect to the patented inventions in the United States without authority from Welch Allyn and during the term of the '492 Patent.

59. Thus, iRhythm is liable to Welch Allyn in an amount that compensates it for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

60. As previously described, iRhythm's infringement has been deliberate, willful and wanton, and with full knowledge, or in the alternative, willful blindness of the '492 Patent, as iRhythm has cited at least one family member of the '492 Patent on the face of several of its issued patents. *See, e.g.*, Ex. 18 at 3 (citing the '007 Patent).

COUNT III

Patent Infringement of U.S. Patent No. 9,155,484

61. Welch Allyn realleges and incorporates by reference the allegations in paragraphs 1–60 of this Complaint.

62. iRhythm makes, uses, sells, and/or offers for sale certain Zio ECG monitoring products including, but not limited to the Zio AT Monitor, Zio XT Monitor, and Zio Monitor. *See* Ex. 6. Any of these individual activities is an act of infringement under 35 U.S.C. § 271(a), and, as set forth in the attached non-limiting Claim Charts (Exs. 23–25), iRhythm directly infringes at least claim 1 of the '484 Patent, either literally or under the doctrine of equivalents.

63. iRhythm has engaged in the foregoing conduct with respect to the patented inventions in the United States without authority from Welch Allyn and during the term of the '484 Patent.

64. Thus, iRhythm is liable to Welch Allyn in an amount that compensates it for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

65. As previously described, iRhythm's infringement has been deliberate, willful and wanton, and with full knowledge, or in the alternative, willful blindness of the '484 Patent, as iRhythm has cited at least one family member of the '484 Patent on the face of several of its issued patents. *See, e.g.*, Ex. 18 at 3 (citing the '007 Patent).

COUNT IV

Patent Infringement of U.S. Patent No. 10,159,422

66. Welch Allyn realleges and incorporates by reference the allegations in paragraphs 1–65 of this Complaint.

67. The claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and 35 U.S.C. § 271.

68. iRhythm makes, uses, sells, and/or offers for sale certain Zio ECG monitoring products including but not limited to the Zio AT Monitor, Zio XT Monitor, and Zio Monitor. *See* Ex. 6. Any of these individual activities is an act of infringement under 35 U.S.C. § 271(a), and,

as set forth in the attached non-limiting Claim Charts (Exs. 26–28), iRhythm directly infringes at least claim 1 of the '422 Patent, either literally or under the doctrine of equivalents.

69. iRhythm actively infringes at least claim 1 of the '422 Patent by manufacturing certain Zio ECG monitoring products. *See* Ex. 6.

70. iRhythm has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from Welch Allyn and during the term of the '422 Patent.

71. Thus, iRhythm is liable to Welch Allyn in an amount that compensates it for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

72. As previously described, iRhythm's infringement has been deliberate, willful and wanton, and with full knowledge, or in the alternative, willful blindness of the '422 Patent, as iRhythm has cited at least one family member of the '422 Patent on the face of several of its issued patents. *See, e.g.*, Ex. 18 at 3 (citing the '007 Patent).

RELIEF REQUESTED

WHEREFORE, Welch Allyn requests that the Court enter a judgment in its favor and against iRhythm and provide Welch Allyn the following relief:

A. Order, adjudge, and decree that iRhythm has infringed the Patents-in-Suit;

B. Order, adjudge, and decree that iRhythm willfully infringed the Patents-in-Suit;

C. Order, adjudge, and decree that iRhythm's infringement of the Patents-in-Suit is exceptional under 35 U.S.C. § 285;

D. Award Welch Allyn damages for patent infringement including prejudgment interest and costs against iRhythm under 35 U.S.C. §§ 284 and 289;

E. Award Welch Allyn up to three times its damages to compensate Welch Allyn under 35 U.S.C. § 284;

F. Award Welch Allyn its reasonable attorneys' fees under 35 U.S.C. § 285; and

G. Award such other and further relief as the Court may deem just including but not limited to an accounting for acts of infringement made but not otherwise awarded to Welch Allyn.

JURY DEMAND

Welch Allyn demands trial by jury.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

Jeffrey R. Gargano
Devon C. Beane
Melissa M. Haulcomb
Rebekah Hill
K&L GATES LLP
70 W. Madison St., Suite 3300
Chicago, IL 60602
(312) 372-1121

Erik J. Halverson
K&L GATES LLP
4 Embarcadero Center, Suite 1200
San Francisco, CA 94111
(415) 882-8200

By: */s/ Philip A. Rovner*
Philip A. Rovner (#3215)
P.O. Box 951
Wilmington, DE 19899
(302) 984-6000
provner@potteranderson.com

Attorney for Plaintiff Welch Allyn, Inc.

Dated: February 20, 2024
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